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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/959,391 10/28/97 GREENHUT

S 3522/E1  
EXAMINER

DM41/0311

ART. UNIT 5  
LAYN, C PAPER NUMBER

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3737  
DATE MAILED:

03/11/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 12/14/98
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1 - 48 is/are pending in the application.  
Of the above, claim(s) 11 AND 12 is/are withdrawn from consideration.
- Claim(s) 1 - 9 is/are allowed.
- Claim(s) 10, 14, 25, 35, 37-39, AND 42-45 is/are rejected.
- Claim(s) 13, 15-24, 26-34, 36, 40, 41, AND 46-48 is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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**DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment which was received by the Office on December 14, 1998. This document has been made of record in the file as Paper No.4.

*Specification*

2. The disclosure is objected to because of the following informalities:  
-p.9, line 31 and p.13, line 32, please replace the blank line with the word "abandoned".  
Appropriate correction is required.

*Claim Rejections - 35 USC § 112*

3. In view of applicant's numerous modifications to the claims and cancellation of claim 12, the Examiner is withdrawing the 35 U.S.C 112 rejections which were made against claims 2-7, 12, 14, 28-30, 32-34, and 44 in the last Office action.

4. The 35 U.S.C 112 2nd paragraph rejections of claims 25, 35, and 37, however, have not been overcome by applicant's amendment and are still outstanding for the following reasons.

In regard to claim 25, the amended claim is still indefinite in that, as written, it still recites the functional step of detecting minute volume without any additional positive structural support.

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To overcome this reference, the Examiner suggests further rewording the claim to read "...said metabolic detector includes means for detecting minute volume as said metabolic parameter".

In regard to claim 35, the claim is indefinite in that the word "adjuring" (line 1) is confusing. The Examiner suggests overcoming this typographical error by substituting the word "adjusting".

In regard to claim 37, the claim is indefinite in that no additional positive structure is recited to support the claimed function of modifying the "level of adjustment" of the pacing rate by the "adjusting circuit". To overcome this rejection, the Examiner suggests using the wording "...wherein said adjusting circuit includes means for modifying the level of adjustment...".

***Claim Rejections - 35 USC § 102***

5. Upon further reconsideration of applicant's amendments to claim 10 , cancellation of claims 11 and 12, and arguments, the Examiner is withdrawing the 35 U.S.C 102(b) rejections of Reuter et al '524 and Bardy et al '425 which were made against claims 10, 11, 23, 26, and 38 in the last Office action.

6. Applicant's arguments with respect to claim 10 have been considered but are moot in view of the following new ground(s) of rejection.

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10, 14, 38, 39, and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Amundson '342.

The Amundson '342 patent describes a pacemaker (Fig.3) which reads upon all of the features of applicant's device, as amended. The Amundson pacer is comprised of an "activity sensor" 10a, a pacing generator 27, a respiration sensor 8a (impedance pneumograph), and a microprocessor 19 which performs the function of applicant's controller. In use, the microprocessor 19 selects which incoming sensor signal to process (i.e. 16 or 17 or another) and formats these into command words which are sent via line 26 to timing "rate adjusting circuitry" 5. Timing circuitry 5 adjusts the pacing rate based upon the respiration signal. Applicant's attention is directed to Fig.2 (col.4, lines 3-13) which shows the device's pacing rate as a function of time. It is divided into three sections A, B, and C of which sections B and C are dependent upon the respiration sensed signals while section A is dependent upon the activity sensor sensed signals. The basic pacing rate may vary depending upon the selection of sensors by microprocessor 19 (col.2, lines 65-bottom and col.3, lines 1-3).

In regard to claim 14, the upper limit peak pacing value is Rp (col.3, lines 23-24) while the lower limit is zero. See Fig.2.

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In regard to claims 38 and 39, the Amundson pacer performs all of applicant's claimed method steps. Applicant's attention is directed to col.4, lines 13-23 for a discussion of "adjusting" the base pacing rate and to col.4, lines 3-13 for "generating" pacing commands.

In regard to claims 42-44, applicant's attention is directed to Fig.2.

In regard to claim 45, the Amundson pacer would inherently perform the claimed function since an increase in the "level of exercise" would inherently involve more strenuous breathing which the pacer would detect and compensate for (col.4, lines 20-23).

***Claim Rejections - 35 USC § 103***

9. Upon further reconsideration of applicant's arguments and amendments to the claims, the Examiner is withdrawing the 35 U.S.C 103(a) rejection of Nappholz et al '740 in view of Bardy et al '425 which was made against claims 1, 2, 10, 23-25, and 38 in the last Office action.

***Allowable Subject Matter***

10. The indicated allowability of claims 14, 39, and 43-45 in the previous action is withdrawn in view of the newly discovered reference cited *supra*.

11. Claims 25, 35, and 37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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12. Claims 13, 15-24, 26-34, 36, 40, 41, and 46-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 1-9 are allowed.

14. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

*Conclusion*

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on M-F from 8:30 AM to 5:00 PM. A voice mail message may be left if desired.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef, can be reached on (703) 308-3256. The current fax number for this Group is (703) 305-3588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

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